DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

November 27, 2006

07-PHI-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stanley Kraftsow, President
Craftmatic Organization, Inc.
2500 Interplex Drive
Trevose, PA 19053

Dear Mr. Kraftsow:

During an inspection of your firm located in Trevose, Pennsylvania on May 24, 2006, through June 13, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures therapeutic AC-powered adjustable beds. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

At the conclusion of this inspection, the FDA investigator presented an Form FDA 483, Inspectional Observations, to Charles B. Chernofsky, Chief Compliance Officer for Craftmatic Organization, and sent another copy by mail to you. Our review of the observations noted in this inspection revealed serious violations of FDA regulations applicable to your products, detailed below. Before addressing these specific violations and your firm's responses to the related Form FDA 483 observations, however, we address the issue of your regulatory responsibility under the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations, which your firm questioned during the inspection and in the two undated letters of response to the observations on the Form FDA 483 from Mr. Chernofsky, received in June 2006 and on July 26, 2006. Specifically, although you hold premarket clearances ([redacted] and [redacted]) for the therapeutic beds that you market, you appear to deny your responsibility for some or all of the regulatory responsibilities of manufacturers under the Medical Device Reporting regulation, 21 CFR Part 803, and the Quality Systems regulation, 21 CFR Part 820, because you describe

Craftmatic as a "relabeler" or "distributor" and not as a specifications developer for these devices.

The regulatory obligations detailed in this letter apply to **manufacturers** of devices. Under the applicable definitions, manufacturers include both relabelers and specifications developers. See 21 CFR 803.3 (definition of *manufacturer* includes any person who either "changes the . . . labeling of a device in furtherance of the distribution of the device from the original place of manufacture" or "[i]nitiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications"); 21 CFR 820.3(o) (definition of *manufacturer* includes but is not limited to those who perform the function of relabeling or specification development).

According to your firm's undated response, "Craftmatic is a Relabeler because it makes health related claims for the bed that the manufacturer, [redacted] do not make." Under your self-characterization, Craftmatic is a manufacturer and is responsible for the obligations of manufacturers under the regulations, because relabelers are manufacturers under both definitions cited above. Moreover, this acknowledgment that Craftmatic makes the health-related claims that bring these beds under the device provisions of the Act provides further evidence that Craftmatic is a manufacturer, because it is Craftmatic's actions in making these claims, made under the Craftmatic name, that result in the propagation of these devices in interstate commerce. In addition, although your 483 responses deny that Craftmatic is a specification developer and claim that Craftmatic is a non-technical "purchaser" of products made by [redacted] other Craftmatic statements indicate a more active role in the specification of the bed. For example, during the inspection, FDA collected Craftmatic promotional materials with the heading "Precision Construction Ensures Durability and Dependability" that state: "Craftmatic designers and engineers adapted a patented style of seating, proven to better distribute the body's weight, to the Craftmatic Adjustable Bed, to provide comfort beyond that of any flat bed." In addition, your 510(k) submission ([redacted]) states: "The Craftmatic Adjustable Beds are currently constructed and manufactured to Craftmatic's performance specifications,...." All of these facts support the conclusion that Craftmatic is a manufacturer within the meaning of both 21 CFR 803.3 and 820.3(o).

As noted, FDA's inspection of your establishment indicated serious regulatory violations. Specifically, this inspection revealed that the devices you market are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

- Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, there are no formal written procedures for the processing of product complaints and the designation of the individual(s) responsible for the evaluation, investigation and documentation of complaints.

  We have reviewed your response and have concluded that it appears to be adequate which will be confirmed during the next inspection of your firm.

- Failure to establish and maintain written procedures to ensure the complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803, Medical Device Reports, as required by 21 CFR 820.198 (a)(3). There is no written procedure addressing this requirement.

  We have reviewed your response and have concluded that it is inadequate in that, for the reasons explained above, your firm is a manufacturer as defined by 21 CFR 820.3(o), and thus is subject to QS regulations including the requirement to evaluate complaints for reportability to FDA under Part 803, Medical Device Reporting.

- Failure to establish and maintain written procedures for implementing corrective and preventive actions to address product nonconformances, as required by 21 CFR 820.100(a). For example, although there is a monthly review of service orders, there is no formal written procedure for identifying and investigating product non-conformances and describing the corrective and preventative actions to be taken to address any product non-conformances that are uncovered.

  We have reviewed your response and have concluded that it appears to be adequate which will be confirmed during the next inspection of your firm.

Our inspection also revealed that your Craftmatic Electric Adjustable Bed devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

- Failure to develop, maintain, and implement written MDR procedures for internal systems for timely and effective identification and evaluation of events that may be subject to MDR requirements and for timely transmission of complete reports to FDA, as required by 21 CFR 803.17(a); Failure to develop, maintain, and implement written MDR procedures for documentation and recordkeeping requirements for information that was evaluated to determine if an event was reportable, as required by 21 CFR 803.17(b) . For

example, your firm had no written MDR procedures at all. In addition, a review of your incident files revealed the following: a report of an incident occurring on [redacted] was caused by the [redacted] of a Craftmatic bed and there was no determination of whether or not any injury was incurred as a [redacted], a report of an incident occurring on an unknown date, [redacted] caused by a [redacted], a report of an incident on [redacted] that a [redacted] caused the [redacted] and a report of an incident occurring on [redacted] alleging that a Craftmatic bed [redacted] and the customer was [redacted]. None of these potential MDR reportable events were adequately investigated, evaluated, or documented to determine if your product may have caused or contributed to the reported injuries and death.

We have reviewed your response and have concluded that it is inadequate in that, as explained above, your firm is a manufacturer and therefore required to comply with these MDR regulations.

- Failure to report to FDA no later than 30 calendar days after the day that you received or otherwise became aware of information that reasonably suggests that a device that you market may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CRF 803.50(a)(1) & (2). For example, your incident files contain a report of an incident occurring on [redacted] was caused by the [redacted] of a Craftmatic bed; this information reasonably suggests a reportable malfunction. Your files also contain a report of an incident occurring on an unknown date, [redacted] caused by a [redacted] information that reasonably suggests a reportable [redacted] and contain a report of an incident on [redacted] caused the [redacted] reasonably suggesting a [redacted].

We have reviewed your response and have concluded that it is inadequate in that, as explained above, your firm is a manufacturer who is required to comply with the MDR regulations and submit to FDA MDR reports.

- Failure to conduct a complete investigation of each event including an evaluation of the cause of the event, as required by 21 CFR 803.50(b)(3). For example, for the three incidents listed above and the following two incidents, there is no documentation of any communication with the users regarding these incidents, no medical documentation pertaining to the incidents, and no documentation of an investigation into the causes of the incidents. The additional incidents, which materials in your files indicated you were made aware of, were a report of an incident occurring on [redacted] resulting in [redacted] and a report of an incident occurring on

[redacted], alleging that a Craftmatic bed [redacted] and the customer [redacted]

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.
Your response should be sent to: James C. Illuminati, Compliance Officer, at the address above. If you have any questions about the content of this letter please contact: James C. Illuminati at (215) 717-3078 or fax (215) 597-8212.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

Thomas D. Gardine

Thomas D. Gardine
District Director
Philadelphia District

jci

cc:

Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Director, Division of Primary Care and Home Health Services